DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 5, 2014

INFOMED SERVICIOS INFORMATICOS S.L.
% Mr. Santiago Sola
General Manager
Via Augusta 158, 4th Floor
08006 Barcelona
SPAIN

Re: K131348
Trade/Device Name: ORTOMED
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 28, 2014
Received: July 31, 2014

Dear Mr. Sola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131348

Device Name
ORTOMED

Indications for Use *(Describe)*
ORTOMED is intended for use by specialized dental practices for capturing, storing and presenting patient images and radiographs and to aid in cephalometric analysis, orthodontic and orthognathic surgery treatment planning and communication as well as case follow-up. Results produced by the software tools are to be interpreted by trained and licensed dental practitioners.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5 – 510(k) Summary

DATE OF SUBMISSION:	2013-04-23
SUBMITTER NAME:	INFOMED Servicios Informáticos S.L.
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DEVICE TRADE NAME:	ORTOMED
COMMON NAME:	Radiological Image Processing System
CLASSIFICATION NAME:	Radiological Image Processing System (21 CFR 892.2050)
PRODUCT CODE:	LLZ
REGULATION DESCRIPTION:	Picture archiving and communications system

PREDICATE DEVICE(S):	Dolphin Imaging (K110430) CS Orthodontic Imaging and CS OMS Imaging Software (K122427)

DEVICE DESCRIPTION:

Ortomed is an imaging software designed for use by specialized dental practices for capturing, storing and presenting patient's dental images and for assisting in treatment planning and case diagnosis, specifically cephalometric tracing for orthodontic and orthognathic cases. Results produced by the software's diagnostic and treatment planning tools must be interpreted by the trained, licensed practitioner. The software features and capabilities include image capture storage and management using the Gesden database and Gesimag image management suite and also specific cephalometric analysis functions and treatment simulation. Features and capabilities include:

- Cephalometric landmarking and analysis: lateral, frontal, models and soft profile
- Analysis of models: Bolton, Moyers, Dentoalveolar discrepancy analysis
- Lateral tracing superimposition, overlays on patient images
- CO/CR conversion, growth forecasts, simulation of facial profile growth
- VTO (Visual Treatment Objective) treatment simulation for orthodontic cases
- STO (Surgical Treatment Objective) treatment simulation for orthognathic surgical cases
- Simulation and display of VTO/STO treatments using warping and morphing.

SUMMARY OF COMPARISON WITH PREDICATE DEVICE:

In the establishment of substantial equivalence, the Software ORTOMED is compared with the following previously cleared device:

- Dolphin Imaging 11.5 (K110430)
- CS Orthodontic Imaging and CS OMS Imaging Software (K122427)

Comparison of the proposed devices with the predicate device is summarized in the following table:

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Characteristic / Feature	Proposed Device ORTOMED	Predicate Device DOLPHIN IMAGING 11.5	Predicate Device CARESTREAM CS
510(k) number	Pending	K110430	K122427
General Features			
Basic Technology Platform	PC-based software application	PC or Mac	IBM-compatible PC or PC network
Operating System	Windows® 2000/XP, Vista and Windows® 7	Windows XP Pro with SP2, 2003 Server, 2008 Server or Windows 7 (supports both 32 and 64-bit versions)	Microsoft Windows
User Interface	Mouse, Keyboard	Mouse, Keyboard	Mouse, Keyboard
Patient Management	GESDEN module for patient registration and file management GESIMAG module for image management.	Imaging Plus Module for patient registration and file management	-
Charting and Reports	Customizable report contents and image layers. Custom formatting Min: 720 dpi color printer	Printer output: Min: 720 dpi color printer Rec: 1440 dpi color inkjet or dye sublimination printer	-
Import / Export capabilities	Paper or electronic formats (PDF or image formats JPEG, PNG, GIF, BMP. Export of complete studies to an exchange file (.OSE). / Import of previously exported studies.	Export to multiple formats, copy images to Windows clipboard, e-mail images DICOM support (optional)	Includes DICOM
Patient Database Engine	Microsoft® SQL©	Microsoft® SQL©	SQL
Image Features			
Image Input Sources	- Digital Radiology devices connected directly to the computer. - Scanner (TWAIN) with backlighting for X-rays. - Digital photography (minimum 3MP camera recommended) - External files from USB, network or	X-rays, slides and other images - Digital x-ray images (optional) - TWAIN –compliant input devices; Flatbed scanner – min. 150 dpi for x-rays, 300 dpi for photographs and 1600 dpi for slides. - Existing files in industry-standard	Images can be scanned, loaded from digital cameras or card readers, or imported from specific interfaced radiographic imaging devices.

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Characteristic / Feature	Proposed Device ORTOMED	Predicate Device DOLPHIN IMAGING 11.5	Predicate Device CARESTREAM CS
	digital camera.	image formats - Creates 2D radiographs from volumetric CBCT data using Dolphin 3D software (optional) - Digital photography (minimum 3MP camera recommended)	
Image manipulation tools	Preview Rotate Enhance ((brightness, contrast, gamma, hue, saturation) Align Zoom in/out, Brightness, contrast, sharpness, emboss	Preview Crop Rotate Enhance (brightness, contrast, gamma, hue, saturation, red-eye reduction) Align Zoom in/out, Brightness, contrast, sharpness, emboss	Greyscale, invert, emboss, brightness, contrast, gamma, sharpen, median, despeckle, hue, saturation, equalize, flip, mirror, masking, rotate, annotation, cephalometric tracing, ceph growth projections, implant simulations.
Image Measurement	Yes (linear distance, angle)	Yes (linear distance, angle)	Yes (linear distance, angle)
Matching / Adjustment of Photograph to X-ray	Yes	Yes	-
Analytical and Planning Functional Features			
Cephalometric Analyses	In addition to user-configured analysis, standard orthodontic tracing analyses include: Lateral Analyses: - Ricketts - McNamara - Steiner (Tweed) - Jarabak - Roth - Downs - Bjork-Williams - Holdaway	Both standard and user-configured analyses may be used. Lateral Analyses: - Ricketts - McNamara - Steiner (Tweed) - Jarabak - Roth - Sassouni - McLaughlin - Downs-Northwestern	In addition to user-configured analysis, standard orthodontic tracing analyses include: - Downs - Jarabek - McNamara - Ricketts - Roth - Sassouni - Steiner - Tweed

Section 5 – 510(k) Summary

Characteristic / Feature	Proposed Device ORTOMED	Predicate Device DOLPHIN IMAGING 11.5	Predicate Device CARESTREAM CS
	- Burstone-Legan - … and many more. Frontal Analyses: - Ricketts Frontal - Frontal M. - HSR Panoramic Models Discrepancy Studies: - Bolton - Moyers - Schwartz-Korkhaus - Transversal - ADS-ADI Cervera Photo studies of soft tissues - Facial profile - Photo/Radiograph Superimposition, Tracing / photo superimposition	- Bjork - Alexander (Vari-Simplex) - Holdaway - Alabama - Burstone - Gerety - … more than 400 in all Frontal Analyses: - Ricketts - Van Arsdale - Grummons - Grummons Simplified Arch Analysis (Models Study) - Bolton - Schwarz Photo Studies of Soft Tissues: - Photo/Radiograph Superimposition, Tracing / photo superimposition	
Cephalometric Tracing	- Automatic landmark insertion, Manual repositioning of landmarks and control points - Automated tooth and cephalometric structure	- Automated tooth and cephalometric structure templates	Yes

Section 5 – 510(k) Summary

Characteristic / Feature	Proposed Device ORTOMED	Predicate Device DOLPHIN IMAGING 11.5	Predicate Device CARESTREAM CS
	templates - Superimposition of tracings	- Superimposition of tracings	
Treatment Planning, Simulation and Follow-up	Orthodontic treatment - Translate, tip and rotate incisors, reposition molars, auto-rotate mandible - Arch length discrepancy worksheet - CO/CR Conversion Growth Forecast (Ricketts algorithm) - Growth simulation on a traced x-ray or tracing overlaid on photograph - Superimpose one or more growth tracings over original tracing VTO – Visual Treatment Objective SVTO – Surgical Visual Treatment Objective (orthognathic surgery) Warping and Morphing	Orthodontic treatment - Translate, tip and rotate incisors, reposition molars, auto-rotate mandible - Arch length discrepancy worksheet - CO-CR conversion Growth Forecast (Bolton or Ricketts growth algorithms) - Growth simulation on a traced x-ray or tracing overlaid on photograph - Superimpose one or more growth tracings over original tracing VTO SVTO (Orthognathic surgery) Movie Morphing	Simulated growth projections on lateral photos used for patient communication.
Implant module	No	Additional module (IMPLANNER™)	Yes – includes implant libraries.
3D image capabilities	No	Optional conversion from 3D volumetric CBCT data to 2D radiographs.	None – includes interface to 3D imaging software provided with specific systems. Does not view, transfer or process 3D radiographs.

Table 5.1 Summary comparison of characteristics and features – proposed and predicate devices.

Section 5 – 510(k) Summary

INTENDED USE:
As established in the Indications for Use Statement:

ORTOMED is intended for use by specialized dental practices for capturing, storing and presenting patient images and radiographs and to aid in cephalometric analysis, orthodontic and orthgnathic treatment planning and case follow-up. Results produced by the software tools are to be interpreted by trained and licensed dental practitioners.

Ortomed has similar intended uses as the predicate devices and has very similar technological characteristics.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:
The proposed device has been designed, developed, tested, verified and validated according to documented procedures and specific protocols in line with the following FDA guidance documents:

- Guidance for the Submission of Premarket Notifications for Medical Imaging Management Devices
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

Design and development included identification, evaluation and control of potential hazards as per standard ISO 14971. Integration, verification and validation testing have been successfully completed following standard ISO 62304.

SUMMARY DISCUSSION OF CLINICAL DATA:
Non-clinical test data are submitted to support this premarket notification and to establish the decision concerning adequate safety and performance of the predicate device.

CONCLUSIONS:
We believe the intended use, the indications for use and performance of the Ortomed software is substantially equivalent to the intended use, indications for use and performance of the predicate device. We also believe that the Ortomed software does not suppose any new or increased risk compared with the predicate device. Based on the information included in this submission, we conclude that Ortomed is substantially equivalent to the listed legally marketed predicate devices.